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PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year)		11.01.2001
Applicant's or agent's file reference 110/01357		REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/IL00/00056	International filing date (day/month/year) 27/01/2000	Priority date (day/month/year) 27/01/1999
International Patent Classification (IPC) or both national classification and IPC A61F2/46		
Applicant DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. et al.		

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☒ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☒ Certain document cited
 - VII ☒ Certain defects in the international application
 - VIII ☒ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.
 - When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).
 - How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
 - Also:** For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.
 - If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 27/05/2001.

Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer / Examiner Josten, S Formalities officer (incl. extension of time limits) Terzic, K Telephone No. +49 89 2399 2052
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Lucia Kert

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International application No. PCT/IL00/00056

I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-25 as originally filed

Claims, No.:

9-99 as originally filed

1-8 as received on 30/08/2000 with letter of 28/08/2000

Drawings, sheets:

1/26-26/26 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 48.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:

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- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 73-89,

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
 - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
 - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
 - ☒ no international search report has been established for the said claims Nos. 73-89.
2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the standard.
 - ☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.

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- ☒ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:
3. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this opinion:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1-72, 90-99.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement
- | | | |
|-------------------------------|--------|--------------------------------|
| Novelty (N) | Claims | 1-72, 96 (yes), 90-92, 94 (no) |
| Inventive step (IS) | Claims | 1-72, 96 (yes), 93, 95 (no) |
| Industrial applicability (IA) | Claims | |
2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)
and / or
2. Non-written disclosures (Rule 70.9)
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

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see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. As to independent claim 1, none of the documents cited in the search report discloses a force application mechanism for applying deforming force to the implant, by axial motion of a force applicator against the implant. The documents US-A-5759186 (=D1), US-A-5782838 and US-A-5683451 each describe self-expanding implants and there is therefore no need for applying a deforming force to the implant.

Thus, claim 1 at present appears to meet the requirements of Articles 33(2) and 33(3) PCT. Since claims 2 to 72 are dependent from claim 1 these claims also appear to meet the requirements of Articles 33(2) and 33(3) PCT.

2. As to independent claim 90, the document US-A-5171248 (=D2) is considered to represent the closest prior art.

D2 discloses (see figure 4) a measurement apparatus for taking measurements inside the body (see column 1, lines 56 to 58), comprising:
a hollow tube 12, defining at least one slot 24, 26 at its end;
a shaft 28 disposed within said tube 12; and
at least one wing 32, 34 coupled to said shaft 28 and adapted to extend through said slot 24, 26, wherein an extension position of said wing 32, 34 determines an axial motion of said shaft in said tube,
wherein said apparatus is adapted to come in contact with body fluids and
wherein said apparatus is sterile.

Thus, all features of claim 90 are known from D2 and the claim, therefore, does not meet the requirements of Article 33(2) PCT.

3. The features of claims 91, 92, and 94 are also known from D2. Thus, these claims do not meet the requirements of Article 33(2) PCT.
4. The features of claims 93 and 95 cannot be seen as involving an inventive step

since they relate to slight constructional changes of the apparatus known from **D2** which come within the scope of the customary practice followed by persons skilled in the art. Thus, claims 93 and 95 do not meet the requirements of Article 33(3) PCT.

5. The features of claim 96 at present cannot be derived from the available documents. Thus, Claim 96 and claims being dependent therefrom at present appear to meet the requirements of Articles 33(2) and 33(3) PCT. Reference is made to item VIII, paragraph 11.

Re Item VI

Certain documents cited

6. The priority 27.01.99 claimed by the present application has not been checked. The document WO-A-9939661 (filing date 05.02.99; priority date 05.02.98; publication date 12.08.99) is of particular relevance. The document WO-A-952446 (filing date 09.04.99; priority dates 09.04.98 and 27.10.98; publication date 21.10.99) is not considered to be of particular relevance.

Re Item VII

Certain defects in the international application

7. The application does not meet the requirements of Rule 6.3(b) PCT since the independent claims should be properly cast in the two-part form, with those features which in combination are known from **D1** being placed in the preamble of claim 1 and with those features which in combination are known from **D2** being placed in the preamble of claim 90.
8. The application does not meet the requirements of Rule 6.2(b) PCT since reference signs in parentheses should be inserted in the claims to increase their intelligibility. This applies to both the preambles and characterising portions.
9. The application does not meet the requirements of Rule 5.1(a)(ii) PCT since

documents **D1** and **D2** should be cited in the description and the relevant background art disclosed therein should be briefly discussed.

Re Item VIII

Certain observations on the international application

10. Claim 1 is not fully supported by the description (Article 6 PCT) since it is not clear which features shown in the figures or mentioned in the description do form the force application mechanism and the synchronizer cited in claim 1.
11. As can be seen from figures 5A to 5C and from the description on page 16, line 20, wings 208 form a parallelogram. Thus, claim 96 should be clarified (Article 6 PCT) by stating that **two wings (208)** define a parallelogram.